K033145
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510(k) Summary of Safety and Effectiveness for the Hoffmann® II Pelvic Clamp

Proprietary Name:	Hoffmann® II Pelvic Clamp
Common Name:	External Fixation Frame Component
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 LXT
For Information contact:	Vivian Kelly, Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	September 29, 2003

Intended Use:
This submission describes an external fixation frame component for use with the components of the Hoffmann® External Fixation System, Hoffmann® II External Fixation System and Monotube Triax™ External Fixation System and in conjunction with Apex® Pins. External fixation frames are intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

Description:
The subject Hoffmann® II Pelvic Clamp is used with the components in the Hoffmann® External Fixation System, Hoffmann® II External Fixation System and Monotube Triax™ External Fixation System to stabilize fractures of the pelvis using Apex® Pins. The Hoffmann® II Pelvic Clamp is a modification of the Hoffmann® 30 Degree Pelvic Double Ball Joint and is made from stainless steel and aluminum with threaded locking bolts.

Substantial Equivalence:
Equivalency of this device is based on similarities in intended use, materials and design to the predicate device. Testing has been conducted on the Hoffmann® II Pelvic Clamp demonstrating substantial equivalence to the predicate 30 Degree Pelvic Double Ball Joint.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Ms. Vivian Kelly
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K033145
Trade/Device Name: Hoffman® II Pelvic Clamp
Regulation Number: 21 CFR 3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: LXT
Dated: September 29, 2003
Received: September 30, 2003

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 033145

Device Name: Hoffmann® II Pelvic Clamp

Indications For Use:

The Hoffmann® II Pelvic Clamp is an external fixation frame component for use with the components of the Hoffmann® External Fixation System, Hoffmann® II External Fixation System, Monotube® TRIAX™ External Fixation System and in conjunction with Apex® Pins. It is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milleren

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033145